INVESTIGATORS:

PLEASE SIGN AND DATE PAGE 1 & 2 OF THESE VERIFICATION FORMS TO OBTAIN HRPP TRAINING CREDIT

DEPARTMENT OF VETERANS AFFAIRS

Memorandum

From: Chief, Research Compliance & Education
Subj: Training Materials and Information Concerning the Use of Human Subjects in Research (HRPP Training)
To: All Human Studies Investigators and Research Coordinators

1. In accordance with the guidelines set forth in the Syracuse and Canandaigua VAMCs' *Federal Wide Assurance with the Department of Health and Human Services for Protection of Human Subjects*, the VA Research Administration office must provide each individual conducting human subject research with the enclosed documents. This memo serves to document your attendance at this training session on Human Subject Protections and serves to document your receipt of the following documents:

A. one copy of the Syracuse and/or Canandaigua VAMC's *Federal Wide Assurance of Protection for Human Subjects from the Department of Health and Human Services;*

B. one copy of *The Belmont Report*, Ethical Principles and Guidelines for the Protection of Human Subjects of Research;

C. one copy of the Department of Health and Human Services (DHHS), Title 45 Code of Federal Regulations, Part 46;

D. one copy of the Food and Drug Administration (FDA), Title 21 Code of Federal Regulations, Part 50;

E. one copy of FDA, Appendix E, Significant Differences in FDA and HHS Regulations for Protection of Human Subjects;

F. one copy of the VA Handbook 1200.5, dated July 15, 2003, *Requirements for the Protection of Human Subjects in Research*;

G. one copy of the Syracuse VA R&D Service Standard Operating Policy 151-02, *Policies and Procedures for Research with Human Subjects;*

H. one copy of the Syracuse VA R&D Service Standard Operating Policy 151-05, *Misconduct in Scientific Research;*

I. one copy of the CPRS electronic progress note templates for research subjects;

J. web address and memo regarding the Collaborative IRB Training Initiative (CITI) Online Course in The Protection of Human Subjects (Web address: http://www.citiprogram.org and the VA Good Clinical Practice (GCP) online tutorial (Web address: http://www.va.gov/resdev/fr/PRIDE/training/gcp-hsp-instructions.cfm).

K. one copy each of Mr. James Cody's memo on Human Subject Research Compliance and the Education Verification Form, to be signed, dated and returned to Dr. Catherine Vernon or Tammy Sandidge;

L. one copy of the Syracuse VAMC Scope of Practice for Research Coordinators, to be completed, signed, approved and returned to C. Vernon or T. Sandidge (Research-151), if applicable.

M. one copy paper Informed Consent completion hints;

2. Please retain these documents for future reference when utilizing human subjects in research activities. Please sign the bottom of this memo and return it to **C. Vernon or T. Sandidge, VA Research (151).** Feel free to contact me at (315) 425 4400 X53539 with any questions regarding these documents.

I, _____ *(print name)*, attest to attending the Syracuse VA Utilizing Human Subjects in Research training session and receiving the listed materials. I understand my responsibilities as an individual utilizing human subjects in research at the Syracuse and/or Canandaigua VA Medical Center. By signing this document I agree to review and abide by the above policies and procedures of the Syracuse VAMC Human Studies Subcommittee. If I am uncertain of any of this information, I understand that it is my responsibility to contact the Research Office for clarification at (315) 425-4400 X53539 or email me at Catherine.Vernon@med.va.gov.

_____ _____
SIGNATURE DATE
E-MAIL: _____ SSN: _____

Department of Veterans Affairs

MEMORANDUM

Date: January 2006

From: Syracuse VAMC Director (00)

Subj: Human Subject Research Compliance

To: All Research Staff

1. I am hereby notifying all investigators and other personnel involved in human research studies of the following:

    a) If you conduct research without IRB approval, it will affect your standing in the VA, and
    b) You will be held responsible for ethical breaches in the conduct of your research, and
    c) You will be held responsible for any procedural breaches in the conduct of your research.

2. Any of these problems may affect your ability to do research with the VA in the future, and will result in administrative action.

3. Thank you for your anticipated cooperation in continuing to support a research service of high quality.

JAMES CODY

_____ _____

Printed Name **Signature**

_____

Date of Receipt